NICE National Institute for Health and Care Excellence

NICE

The guidelines manual: appendix A – agreements and advice for Guideline Development Group members

Tailored service improvement support

Published: 30 November 2012
nice.org.uk

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A1 Code of conduct for Guideline Development Group (GDG) members and others who attend GDG meetings

A1.1 Key principles of development

NICE's clinical guideline development process:

- involves and consults with national patient, service user and professional organisations (such as GDG members and stakeholders)
- involves companies that manufacture relevant medicines or devices, and the Department of Health and the Welsh Government (as stakeholders)
- uses robust and transparent methodologies
- produces guidance that is based on the best available clinical and economic evidence, and is clearly explained.

GDGs should ensure that clinical guidelines cross-refer to or incorporate any relevant recommendations from NICE's other guidance programmes (for example, technology appraisal, interventional procedures or public health guidance), and should also take into account recommendations from appropriate national service frameworks (NSFs). Each GDG should ensure that its guideline is developed in line with these requirements. It should also follow the principles set out in Social value judgements: principles for the development of NICE guidance (second edition) and adhere to the NICE equality scheme.

A1.2 Status of GDG members

Members are appointed to a GDG either by virtue of their relevant experience (as in the case of patient, service user and carer members, and healthcare professional members) or because they have specific technical skills (as in the case of systematic reviewers and health economists). If members are from stakeholder organisations, NICE and the GDG assume that these members bring this perspective to the group, but do not represent their organisations. GDG members are appointed for the duration of the development process for a clinical guideline.

People appointed to the GDG are co-authors of the guideline. They will respect the rights of NICE both to publish the final guideline documents and to receive notification of associated publications, as described in contracts with the National Collaborating Centres (NCCs).

A1.3 Mutual undertaking

NICE, usually through one of its NCCs, undertakes to:

- ensure that the GDG is properly resourced to produce the guideline
- provide all members of the GDG with equal access to available resources and to the evidence used in the development of the guideline
- offer appropriate training to GDG members to enable them to play a full part in the development of the guideline
- provide technical support during the development of the guideline.

GDG members undertake to:

- make sufficient time available to attend meetings and properly inform the development of the guideline through their personal and professional knowledge and, where appropriate, their organisation's perspective
- provide the GDG, and subsequently (and only after failure to resolve the issue within the GDG) the NCC and NICE, with the opportunity to consider and resolve concerns or disagreements about either the process or the detail of the emerging guideline
- contribute positively to the work of the group and the development of the guideline.

A1.4 Transparency

NICE believes that its guidance will be enhanced if those who are intended to benefit from it and those who have the responsibility for implementing it have had the opportunity to be involved in its development.

For GDGs to operate successfully, they need to be able to develop and debate issues within the group before exposing them to wider comment. There is therefore a need for arrangements that protect the confidentiality of documents and discussions.

In order to provide the environment described above, NICE expects GDG members:

- to be aware that the Guidance Executive and Senior Management Team at NICE will not comment on the development of a guideline in progress, other than in the context of the formal consultation exercises

- to regard the views expressed by individual members of the GDG as confidential
- to regard the documents used and discussions held by the GDG as confidential to the group until public consultation, as stipulated in the 'Confidentiality acknowledgement and undertaking' agreement (see appendix A2)
- not to discuss commercial-in-confidence data outside the GDG
- to respect the confidentiality of documents supporting a published or unpublished technology appraisal and guidelines in development if such documents are received by the GDG
- to respect the confidentiality of documents relating to other unpublished NICE guidance (such as interventional procedures, medical technologies or public health guidance) if such documents are received by the GDG.

GDG members are also expected to adhere to NICE's policy for declaring conflicts of interest (see also section A4.4).

A2 Participation in NICE guidelines: confidentiality acknowledgement and undertaking

Please complete the sections below and return by email to: [insert NCC email]

If email is not possible, please return by fax to: [insert NCC fax no.]

This agreement covers all those who have sight of documents, or are party to discussions, relating to a guideline before public consultation. This includes members of the Guideline Development Group (GDG), invited external experts, observers and participants in consensus exercises. Staff of National Collaborating Centres (NCCs) are covered by the contracts between NICE and the NCCs.

1) I undertake to NICE that I shall:

(a) keep all confidential information strictly confidential

(b) not use any confidential information for any purpose other than participating in the deliberations of the GDG (for GDG members and external experts)

(c) not disclose any confidential information to any third party without the prior written consent of NICE

(d) not disclose the deliberations of a GDG to any other person without the explicit consent of the Chair of the GDG and the Director of the NCC.

2) The undertakings set out in paragraph 1 above ('the undertakings') shall not apply to the use or disclosure of information that:

(a) at or after the time of disclosure or acquisition is in the public domain in the form supplied otherwise than through a breach of any of the undertakings; or

(b) was lawfully within my possession before its disclosure to me by NICE, provided that the source of such information was not bound by, or subject to, a confidentiality agreement with NICE; or

(c) I am required to disclose by any court of competent jurisdiction or any government agency lawfully requesting the same, provided that I notify NICE in advance of such disclosure; or

(d) is approved for release by prior written authorisation from NICE.

Signed ……..Date ……..

Print name ……

Data Protection. The personal data submitted on this form will be used by the National Institute for Health and Clinical Excellence for work on its Guidelines Programme and will be held on the Institute's databases for future reference and in accordance with the Data Protection Act 1998.

A3 Dealing with enquiries on GDG work

A3.1 Introduction

As a member of a GDG you will be considered by some to be a source of information, to have important influence or to be a lobbying target. This guidance will help you to deal with any enquiries you receive from individuals or organisations about your work on the GDG.

Although NICE will not publish your contact details anywhere, your name and the organisation that supported your application (if appropriate) will be published on the NICE website. Thus it may be easy for those who want to contact you to do so.

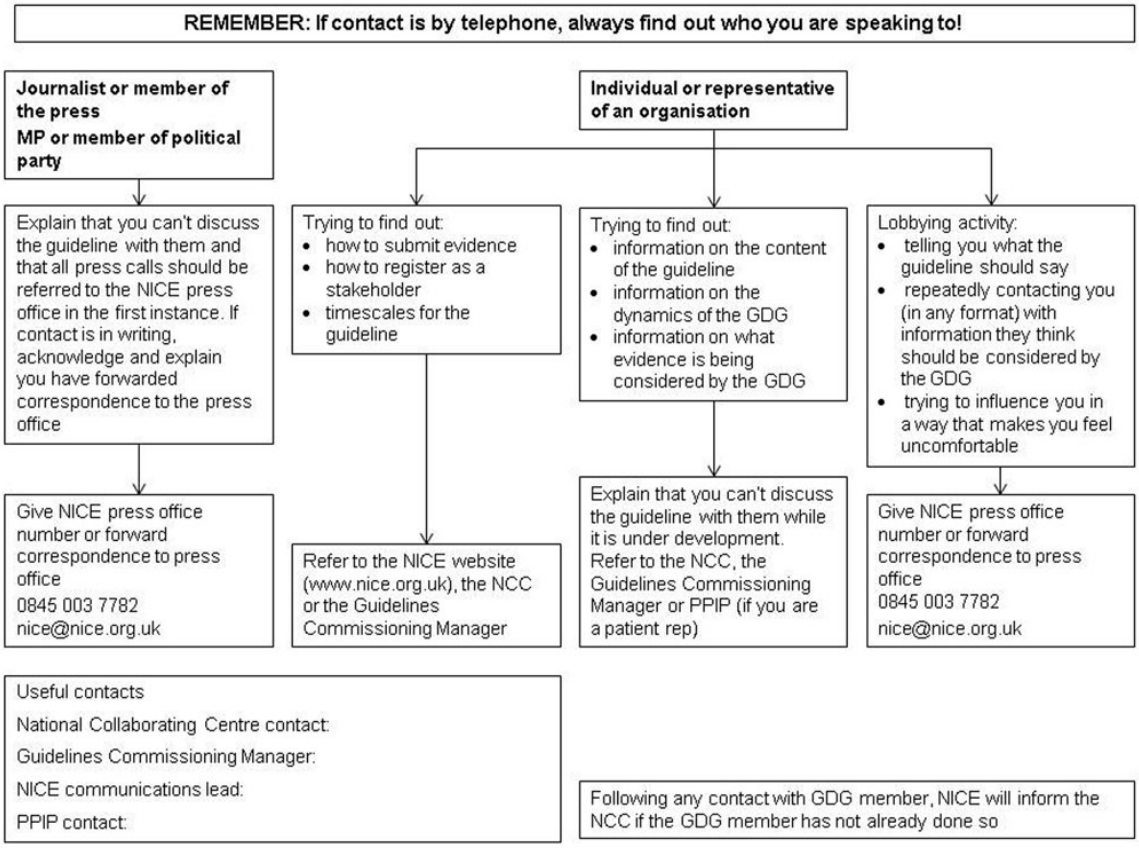
Just like the guideline you are developing, this document is guidance, not 'must do', and has been developed to support you in handling enquiries so that you do not feel obliged to deal with them yourself.

A3.2 Golden rules

Some things to remember when talking to anyone about the guideline you are developing:

- Don't feel that you have to talk to anyone about the guideline: you can handle requests for information by offering to pass them on to someone who is able to deal with them (such as your lead contact at the NCC, the NICE Guidelines Commissioning Manager or the NICE communications lead).
- Don't speculate on the content of the guideline before it is finally published.
- Draft versions are just that: draft, not final; the content may change after consultation.
- Individuals and organisations can influence the outcome of the guideline only by submitting evidence that supports their point of view as part of the formal consultation process.
- You have not been selected to sit on the GDG to represent all patients, service users, clinicians, nurses or other healthcare professionals. You are there to provide your own expert opinion to the group.
- In the unlikely event that you are contacted by telephone by an unpleasant or demanding caller, offer to pass the enquiry on to your NCC or NICE contact. Then tell the caller politely but firmly that you wish to end the call. If the caller persists, put the phone down.

A3.3 Flow chart for dealing with enquiries



A4 Guidance for Guideline Development Group (GDG) members on attendance at NICE Appraisal Committee meetings

A4.1 Introduction

Before invitations to participate in a NICE technology appraisal are sent out, the Guidelines Commissioning Managers are contacted to establish whether a related clinical guideline is on the work programme, and if so, who should act as representative(s) of the guideline. Members of the GDG – usually the GDG Chair (or the expert with the most relevant experience) and one other member (usually the NCC Director, the Clinical Adviser or another senior clinician) – are invited to attend the appraisal consultation document (ACD) and final appraisal determination (FAD) meetings of the Appraisal Committee considering any appraisal that is relevant to the development of the guideline.

When the topic of the appraisal relates to a guideline on the work programme for which development has not yet begun (that is, there is no GDG in place), the NCC Director should be invited to attend on behalf of the future GDG.

Project managers from the appraisals and guidelines programmes at NICE will liaise at an early stage in each appraisal to determine appropriate links between the relevant committees and GDGs, and to provide operational support.

A4.2 Purpose of attendance and role

The attendance of GDG members at the Appraisal Committee meeting allows them to participate fully in discussions about the technology. They can remain for the concluding discussions of the Appraisal Committee after the patient experts and clinical specialists have left the meeting.

The GDG members attending the Appraisal Committee meeting will also, in conjunction with their GDG as a whole, act as commentators on the documents produced. They will receive the ACD and FAD, and the GDG comments fed back via the NCC will be included in the review of the documents by the technical lead and the Appraisal Committee Chair, and be brought to the attention of the Appraisal Committee.

As is the case for other commentators, GDG members do not have the right of appeal.

A4.3 Voting

In the event of a decision of the Appraisal Committee being taken by a vote, the GDG members attending the meeting will not have the right to vote.

A4.4 Conflicts of interest

GDG members who attend the Appraisal Committee meetings will be expected to declare conflicts of interest and to abide by the current rulings on these for full committee members if they wish to take part in all of the Committee's discussions.

GDG representatives who attend Appraisal Committee meetings do so as committee members (except for voting; see section A4.3). Therefore a GDG representative with a personal pecuniary interest will not be able to attend the Appraisal Committee discussion.

GDG members who have conflicts of interest that would have excluded Appraisal Committee members can be present at meetings only for the same period as the clinical specialists and patient experts, and must leave the room with them before the concluding discussions. This would require their nomination as clinical specialists by the Appraisals' consultees and commentators. Such specialists are only usually present at the first Appraisal Committee meeting (that is, the meeting to develop the ACD).

A4.5 GDG members as clinical specialists or patient experts

GDG members may occasionally also be nominated as clinical specialists or patient experts for an appraisal. They may then act in both capacities, but must leave the meeting with the other specialists and experts if they have a conflict of interest (see section A4.4). GDG members may wish to avoid this dual role in order to maximise their attendance at Appraisal Committee meetings. Exclusion from the second half of the meeting because of conflicts of interest does not preclude GDG members who have attended from providing written comments during consultation.

A4.6 GDG comments on the ACD and FAD

It is expected that the GDG comments on the ACD and FAD will represent a consensus view, expressed in a single document, preferably submitted via the GDG Chair and coordinated by the NCC.